UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,182	08/07/2003	Christopher A. Thierfelder	AMS-161	1760

7590 05/20/2008

Attention: Jeffrey J. Hohenshell
AMS Research Corporation
10700 Bren Road West
Minnetonka, MN 55343

EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
05/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,182	THIERFELDER ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/26/2008 has been entered.

Acknowledgements

2. This office action is in response to the reply filed on 3/26/2008.

3. In the reply, the Applicant amended claims 13, 14, 16.

4. Thus, claims 13-16 remain pending for examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 recites the limitation that the coating comprises polylacticglycolic acid microspheres including dexamethasone. The

specification does not describe using that polylacticglycolic acid microspheres including dexamethasone as a coating on the catheter (see paragraphs 56). The specification does not recite polylacticglycolic acid microspheres including dexamethasone as acting as a substance that is delivered to the ports for resisting the fibrous occlusion of the drug delivery ports, but not as a coating on the catheter. The Examiner suggests deleting the claim recitation. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise et al (5752930) in view of Urry (5519004). Rise et al discloses an implantable drug delivery system comprising: a storage area (19; Fig 4) for storing a drug, a meter for metering a predetermined, effective amount of the drug; delivery means for (Summary, col 2, lns 66-col 4 lns 34) delivering the effective amount of the drug to a patient to treat a disorder, the delivery means comprising: a catheter having a plurality of drug delivery ports (172), the drug delivery ports being movable between an open position to deliver the drug to the patient, and a closed position (172, Summary). However, Rise et al does not expressly disclose drug delivery path preservation means comprising a coating on the catheter for interacting with fibrous occlusion-forming substances to resist fibrous

occlusion of the drug delivery ports and wherein the coating comprises poly(glycine-valine-glycine-valine-proline).

9. Urry teaches that it is known to have drug delivery path preservation means comprising a coating (col 3, lns 26-col 4, lns 14; col 7, lns 10-13, col 8, lns 56-col 10, lns 20) on the catheter (col, 3, ln 45) for interacting with fibrous occlusion-forming substances to resist fibrous occlusion of the drug delivery ports and wherein the coating comprises poly(glycine-valine-glycine-valine-proline) for the purpose of low propensity of adhesion of proteins, cells, and other biological components that can result in impaired functioning (col 3, lns 26-col 4, lns 14; col 7, lns 10-13, col 8, lns 56-col 10, lns 20; wherein the Examiner notes that poly (GVGVP) is disclosed as resisting the formulation of adhesion of cells and macromolecules). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable drug delivery device as taught by Rise et al with the drug delivery path preservation means as taught by Urry for the purpose of the purpose of low propensity of adhesion of proteins, cells, and other biological components that can result in impaired functioning.

10. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil, Jr. (5041107) in view of Urry. Heil, Jr. discloses an implantable drug delivery system (10) having a storage area (14; col 5, lns 29-38) for storing a drug; a metering for metering a predetermined, effective amount of the drug though a drive electrode (22), a power source (12) and oppositely charged return electrode (26) (col 2, lns 8-56;

col 4, lns 16-30); a delivery means for delivering an effective amount of drug comprising a catheter (14) having a longitudinal axis (Fig 1) and having a plurality of drug delivery ports (22, 32, 44) being a plurality of slits (22, 32, 44) that are movable between an open position to delivery the drug to the patient and a closed position (col 3, lns 54-56; col 4, lns 7-9; col 4, lns 16-30). Further, Heil, Jr recognizes and is directed to provide an improved drug delivery catheter that combats and functions through anticipated tissue encapsulation.

11. However, Heil, Jr. does not expressly disclose drug delivery path preservation means comprising a coating on the catheter for interacting with fibrous occlusion-forming substances to resist fibrous occlusion of the drug delivery ports and wherein the coating comprises poly(glycine-valine-glycine-valine-proline). Urry teaches that it is known to have drug delivery path preservation means comprising a coating (col 3, lns 26-col 4, lns 14; col 7, lns 10-13, col 8, lns 56-col 10, lns 20) on the catheter (col, 3, ln 45) for interacting with fibrous occlusion-forming substances to resist fibrous occlusion of the drug delivery ports and wherein the coating comprises poly(glycine-valine-glycine-valine-proline) for the purpose of low propensity of adhesion of proteins, cells, and other biological components that can result in impaired functioning (col 3, lns 26-col 4, lns 14; col 7, lns 10-13, col 8, lns 56-col 10, lns 20; wherein the Examiner notes that poly (GVGVP) is disclosed as resisting the formulation of adhesion of cells and macromolecules). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable drug delivery device as taught by Heil, Jr. with the drug delivery path preservation means as taught by Urry for

the purpose of the purpose of low propensity of adhesion of proteins, cells, and other biological components that can result in impaired functioning.

Response to Arguments

12. Applicant's arguments with respect to claims 13-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767